K090138

510(k) Summary

APR 24 2009

AFrame Digital

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Purpose: Traditional 510(k) Notification

Device Type: MobileCare Monitor™ is intended for monitoring residents in a long-term care facility. The product is intended to be a monitoring and alerting system similar to many commercially available panic button systems. This product adds location information and an impact sensor that may indicate a fall. Per FDA Request for Information # C070224 (See Appendix A), this is considered a Patient Bed Monitor, a Class I device, classification code KMI.

Date: December 17, 2008

510(k) Submitter: AFrame Digital, Inc.
8000 Lee Highway, 2nd Floor
Falls Church, VA 22042
Owner/Operator#: 10028071
510(k) #: K090138

510(k) Contact: Sunil Saxena, MD
Chief Medical Officer
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Falls Church, VA 22042
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Indications For Use: The MobileCareTM Monitor 2100 system includes a MyPHDTM personal help device that is intended to monitor residents in home and long-term care facilities including independent living, assisted living and rehabilitation settings. The monitor can be placed on the wrist using the Velcro strap and used like a watch by the resident. The other form of

MyPHD offered has no wrist straps so it can be clipped to the waist or used in a bandage for attachment at other locations on the person as may be appropriate or preferred by the user or healthcare provider. The system provides an alert to designated caregivers or professional staff automatically at pre-set thresholds to indicate an impact has occurred. The system also includes an emergency (panic) button that can be pressed by the monitored individual to alert caregivers as needed. The users of the system include staff and residents. The product is intended to be used on a 24-hour basis. The system is not intended to provide automated treatment decisions, nor is it to be used as a substitute for professional healthcare judgment. All patient medical diagnosis and treatment are to be performed under direct supervision and oversight of an appropriate healthcare professional.

Trade Name: MobileCare™ Monitor

Common Name: MobileCare™ Monitor

Classification: Monitor, Bed Patient, (21 CFR 880.2400, Product Code KMI)

Product Code: KMI (21 CFR 880.2400)

FDA Docs: Request for Information # C070224 (Appendix A)

Basis: New Submission

Design & Use of the Device: (Refer to Table 1 below)

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?		X
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?	X	
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?		X
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		N/A
Does the device contain a drug?		X
Does the device contain a biologic?		X

Does the device use software?	X	
Does the submission include clinical information?		X
Is the device implanted?		X

Comparison to Predicate:

Substantially Equivalent Device

The AFrame Digital, Inc. MobileCare™ Monitor is substantially equivalent to the Stanley Security Solutions, Inc., Senior Technologies Div. TABS Elite and Wireless TABs Bed and Chair Exit Monitor System and the Care Electronics WanderCare T100.

Basis of Substantial Equivalence

Per FDA Request for Information # C070224 (See Appendix A), this is considered a Patient Bed Monitor, a Class I device, classification code KMI. The AFrame Digital MobileCare™ Monitor is similar to the primary predicate monitor device with respect to technical characteristics and performance in the following ways.

General Technical Characteristics	Stanley Security Solutions, Inc. Senior Technologies Div. TABS Professional monitors w/Wireless TABS System (Reg. 1929691)	Care Electronics, Inc. WanderCare (K925529)	Proposed device (MobileCare™ Monitor myPHD™)
Attribute			
Indications for use	TABS System is designed to notify staff that a patient is leaving a bed, chair, room or wheelchair, by identifying which monitor is alarming so staff can go directly to the resident in need of assistance.	WanderCare provides monitoring of a wanderer in the home. The system alerts the caregiver when the wanderer goes beyond a set range and provides location tracking capability up to one mile so that the wanderer can be located and returned.	The MobileCare™ Monitor System is designed to notify healthcare providers and caregivers to know when a patient requests assistance or experiences an impact that may be due to a fall, and their location, so staff can go directly to the resident in need of assistance.

Prescription	No	No	No
Intended population	Long Term Care, Assisted Living Residential, Rehabilitation and Home Settings with patients at risk for falls and in need of other assistance	Wanderers (wandering individuals) in the home or in facilities.	Long Term Care, Assisted Living Residential, Rehabilitation and Home Settings with patients at risk for falls and in need of other assistance
Intended Environment of Use	Home, Clinic	Home, Clinic	Home, Clinic
Design			
Method of data collection	Proprietary Software	Proprietary Software	Proprietary Software
Communication method with Care Mgmt and Nurse Call System	Wireless	Wireless	Wireless
Types of sensors which can be interfaced to receiver hub	Pressure sensors in bed and chair pads, door monitors, magnetic locks, smoke detectors, door/window transmitters, motion detectors, nurse call transmitters	Transmitter	Accelerometers, impact detectors, door monitors, motion detectors, and nurse call button
Connectivity	Wireless to hub	Wireless Transmitter to Receiver Antenna	Wireless mesh to hub
Communication method of hub with devices	900 Mhz Spread Spectrum	RF approx 200-500 MHz	2.4 Ghz Zigbee v3.2 (IEEE 802.15.4)
Communications protocol	Proprietary	Proprietary	Zigbee v3.2 (IEEE 802.15.4)
Wireless frequency	900 Mhz Spread Spectrum	RF approx 200-500 MHz	2.402 to 2.480 GHz (FHSS) ISM Band
Power Source	Wall plug for hub (a/c) and 9V battery for 510(k) approved sensor devices.	9V battery for transmitter	Wall plug for hub (a/c) and batteries for 510(k) approved sensor devices and myPHD™
Form Factor	Pressure Pad under bed or chair	"Fanny Pack" worn at the waist with transmitter and 9V battery assembly inside.	Wrist watch or as a small case for attachment to clothing at torso or under a bandage.
Display	Low battery indicator on unit. Flashing light indicating source of call. Sensor devices connect	No display on Fanny Pack. LCD display on Care	On myPHD™ watch display in normal mode or flashing indicator if activated

	to Remote Nurse Call System annunciator.	management system for caregiver.	and also on remote care management system
Alerts	Audible alarm at bedside when sensor activated	Alerts wirelessly to care management system for caregiver.	Alert silently (vibration) or audibly to caregiver or nurse at bedside or remotely when sensor activated
Alert reset	Manual and Automatic when pressure is re-applied (e.g. patient returns to bed)	Manual or Automatic when person returns to area.	Manual or Automatic upon caregiver acknowledgement of activation.
Materials			
	Common plastic materials for human use	Common plastic case for human use.	Common plastic materials for human use

1. **Non Clinical substantial equivalence**
   a. Safety – The safety of the device is demonstrated conformance to the following standard:
      FCC "Code of Federal Regulations" Title 47, Part 15, Subpart B, for receivers and Subpart C, Section 15.247 for Digital Modulation Intentional Radiators Operating within the band 2400-2483.5MHz
      A copy of the engineering test report demonstrating compliance with the above is contained in Appendix B of this submission
   b. Performance – The performance of the device is demonstrated through the validation of the software. A summary report of this software validation is included as Appendix D of this submission.

2. **Conclusion:**

The information in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to devices already in commercial distribution. Equivalence is demonstrated through intended use, design and testing methods.

3. **Similarities/Differences of the proposed device when compared to the predicate:**

The data within this submission demonstrates that there are no significant differences between the application device and the predicate, indicating that the application device is safe, effective and substantially equivalent for marketing in the U.S.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 24 2009

Sunil Saxena, MD
Chief Medical Officer
AFrame Digital, Incorporated
8000 Lee Highway
2nd Floor
Falls Church, Virginia 22042

Re: K090138
Trade/Device Name: MyPHD™ MobileCare™ Model 2100
Regulation Number: 21 CFR 880.2400
Regulation Name: Bed-Patient Monitor
Regulatory Class: I
Product Code: KMI
Dated: March 26, 2009
Received: March 31, 2009

Dear Dr. Saxena:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., MA
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090138

Device Name: MyPHD™ MobileCare Monitor™ Model 2100

Indications For Use:

The MobileCare™ Monitor 2100 system includes a MyPHD™ personal help device that is intended to monitor residents in home and long-term care facilities including independent living, assisted living and rehabilitation settings. The monitor can be placed on the wrist using the Velcro strap and used like a watch by the resident. The other form of MyPHD offered has no wrist straps so it can be clipped to the waist or used in a bandage for attachment at other locations on the person as may be appropriate or preferred by the user or healthcare provider. The system provides an alert to designated caregivers or professional staff automatically at pre-set thresholds to indicate an impact has occurred. The system also includes an emergency (panic) button that can be pressed by the monitored individual to alert caregivers as needed. The users of the system include staff and residents. The product is intended to be used on a 24-hour basis. The system is not intended to provide automated treatment decisions, nor is it to be used as a substitute for professional healthcare judgment. All patient medical diagnosis and treatment are to be performed under direct supervision and oversight of an appropriate healthcare professional.

Prescription Use _____ AND/OR Over-The-Counter Use ___X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

~~Concurrence of~~ CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: for K090138